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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,487	03/10/2000	SVEN BERGSTROM	454312-3150	9076

20999 7590 01/02/2002

FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/508,487

Applicant(s)
Bergstrom

Examiner
Rodney P. Swartz, Ph.D.

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22October2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above, claim(s) 1-19, 36-49, 53, 54, 58, 60, 62-64, 66, 71, and 72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-35, 50-52, 55-57, 59, 61, 65, and 67-69 is/are rejected.
- 7) ☒ Claim(s) 67-70 is/are objected to.
- 8) ☒ Claims 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4, 6
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 22October2001, paper#10, is acknowledged.

Applicants elect, with traverse, Invention II, claims 20-35, 50-52, 55-57, 59, 61, 65, and 67-70, drawn to polypeptide and method of immunizing.

Applicant's election with traverse is on the grounds that a search of all of the inventions does not pose a serious burden on the Examiner, and that all of the inventions relate to a single inventive concept. This is not found persuasive because while the searches may overlap, the searches are not coextensive, and the inventions are directed to structurally distinct molecules (DNA, polypeptides) and distinct methods.

The requirement is still deemed proper and is therefore made FINAL.

Therefore, claims 1-19, 36-49, 53, 54, 58, 60, 62-64, 66, and 71-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

2. Claims 20-35, 50-52, 55-57, 59, 61, 65, and 67-70 are under consideration.

Drawings

3. This application has been filed with drawings which are acceptable for examination purposes only. The drawings are objected to for the reasons set forth on the attached form PTO-948.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 20-32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn merely to "a polypeptide fragment". There is no recitation of "isolation" or "purification". Therefore, the claims read on products of nature.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 50-52, 55-57, 61, 67-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a 13 kDa polypeptide purified from *B. burgdorferi*, B313 inducing antibody production in rabbits, does not reasonably provide enablement for vaccines. The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - vaccine compositions for preventing infections by *B. burgdorferi* in all subjects, including humans.

The state of the prior art - subcomponent vaccines against *B. burgdorferi* are known. However, the prior art does not teach the particular subcomponents in the instant claims as vaccines, and the instant specification provides no examples of vaccines commensurate with the scope of the claims. The instant specification teaches only one example of a composition of a 13 kDa polypeptide purified from *B. burgdorferi*, B313 inducing antibody production in rabbits.

Therefore, the absence of any working examples constitutes merely an invitation to experiment, without a reasonable expectation of success.

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9. Claims 20-35, 50-52, 55-57, 59, 61, and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims all depend from claim 20 which claims "a polypeptide fragment" which reacts with a rabbit antibody raised against "a polypeptide", "said polypeptide" comprising a fragment of SEQ ID NO:19. It is unclear which "polypeptide" comprises the fragment of SEQ ID NO:19, the claimed polypeptide, or the polypeptide used to raise the antibody.

Claim Objections

10. Claims 67-70 are objected to because the claims depend from a non-elected claim.

Appropriate correction is required.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

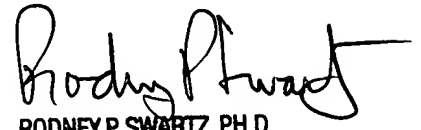
If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
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December 31, 2001